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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/943,144	10/03/97	KOSHIBA	2185.0208P-SP

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EXAMINER	
ZAGHMOUT,O	
ART UNIT	**PAPER NUMBER**
1649	10

DATE MAILED: 12/08/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/943,144	Koshiba
Examiner	**Group Art Unit**
Ousama Zaghmout	1649

☒ Responsive to communication(s) filed on *Sep 17, 1998*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1 and 8-17* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *17* is/are allowed.

☒ Claim(s) *1 and 8-16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *7*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to amendment

The amendment filed 9-17-1998 has been received and entered (paper# 9).

Claims 2-7 are canceled by the Applicants.

Claim 17 is newly added.

Claims 1, 8-17 are pending.

IDS is noted.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

1st Paragraph

Claim 1 and dependent claims 8-16 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The claims are generically drawn to any isolated nucleotide sequence with a single nucleotide or plural nucleotides added, deleted or replaced in any one of (a) to (d) of SEQ ID NO: 1-4 in claim 1. However, the specification discloses SEQ ID NOs: 1-4 only for the isolated aldehyde oxidase. The specification fails to describe adequate representative species of the claimed nucleic acids by their relevant identifying characteristics, e.g. by sequence or other structure or properties. Only the desired SEQ ID Nos:1-4 are disclosed. At the time the application was filed, one of skill in the art could not have predicted the relevant identifying characteristics of the nucleic acids based only on the sequence of the corresponding gene. Accordingly, one of skill in the art would not have recognized the applicant to have been in possession of the claimed antisense nucleic acids at the time the application was filed. Furthermore, there is no information in the literature or in the specification to predict if nucleotide sequences within this genus are very similar in structural and physical characteristics to define the claimed genus. In addition, it is not clear if these claimed but not disclosed nucleic acid molecules will be able provide a protein with biological activity and desirable traits when expressed in a cell. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a

written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

The separateness of the two requirements has been emphasized in the biotechnology area by two cases. Both cases involved interferences in which the count in question related to a strand of DNA. In one case Fiers v. Sugano [25 USPQ2d 1601 (Fed. Cir. 1993], :"An adequate description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself." In the Fiers case, convention priority was denied to a claim to a DNA sequence coding for a specified protein because of the absence of the actual sequence of the DNA in the priority documents. A similar situation occurred in Fiddes v.Baird [30 USPQ2d 1481 (Bd. of Appeals 1993).] where the Board of Appeals stated that "knowledge of amino acid sequence of a protein coupled with the established relationship in the genetic code between a nucleic acid and a protein it encodes would not establish possession of a gene encoding that protein."

Claim 1 and dependent claims 8-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabled for isolation of the nucleotide sequence identified in SEQ ID No: 1-4 of aldehyde oxidase, does not reasonably provide enablement for any isolated nucleotide sequence with a single nucleotide or plural nucleotides added, deleted or replaced in any one of (a) to (d) of SEQ ID NO: 1-4 in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The breadth of the claims are not commensurate in scope with the enabling support provided. Applicants broadly claim any isolated nucleotide sequence with a single nucleotide or plural nucleotides added, deleted or replaced in any one of (a) to (d) of SEQ ID NO: 1-4 in claim 1. However, in the instant disclosure, applicants provide and explicitly demonstrate the isolation of the nucleotide sequence identified in SEQ ID No: 1-4. Applicants provide insufficient guidance as how to isolate other than general indication to go look for it. Applicants failed to address many of these important issues which are essential for the enablement of the claimed invention. Taken together, the instant disclosure lacks the proper and sufficient guidance to enable the claims as set forth. Applicants have provided no specific guidance as to how to isolate other claimed genes which will give the desired effect or provided guidance to isolate nucleotide sequence which will result in a function transcript

when expressed in a cell. One wishing to practice the invention is left to proceed through trial-and-error to see what will work and what will not.

In view of the breadth of the claims, unpredictability, lack of guidance in the specification of the results as stated above, it is the examiner's position that one skilled in the art to which it pertains, or with which it is most nearly connected, could not practice the invention commensurate in scope with these claims without undue experimentations. See also Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene (or promoter) is not reduced to practice until the inventor can define it by " its physical or chemical properties" (e.g., DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof. See also University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Conclusion

Claim 17 is allowed.

Claims 1, 8-16 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraphs, set forth in this Office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner supervisor, Douglas Robinson, can be reached on (703) 308-2897. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.

December 7, 1998

Douglas W. Robinson
Supervisory Patent Examiner
Technology Center 1600